



PATENT  
Attorney Docket No. 402076

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Parikh et al.

Group Art Unit: 1615

Application No. 09/281,430

Examiner: Todd Ware

Filed: March 30, 1999

For: ANTICANCER COMPOSITIONS

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INFORMATION DISCLOSURE STATEMENT

APR 23 2003

Commissioner for Patents  
Washington, D.C. 20231

TECH CENTER 1600/2900

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

**within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

*or*

the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

**after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311; or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

**after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### Copies of the References

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Copies of the references listed on the enclosed Form 1449 are enclosed herewith.

A copy of the foreign search report is enclosed herewith.

The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (check one)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- No fee** is owed by the applicant(s).
- The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- Attached is a check in the amount of \$ . . .
- Charge Deposit Account No. 12-1216 in the amount of \$ . . . (A duplicate copy of this communication is enclosed for that purpose.)

**Authorization to Charge Additional Fees**

- If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

**Instructions as to Overpayment**

Credit Account No. 12-1216.  
 Refund

Respectfully submitted,

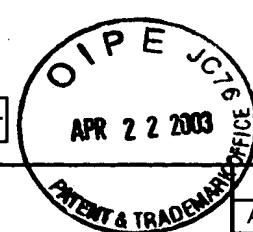
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Date: *April 22, 2003*

IDS (Rev. 7/11/2002)

Please type a plus sign (+) inside this box →



Substitute for form 1449A/B/PTO

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

*Complete if Known*

Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARikh
Group Art Unit	1615
Examiner Name	Todd Ware

Sheet

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of

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Attorney Docket Number

402076 SKYEPHARMA

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A 1	2803582		Cherney	8/20/1957	
	A 2	3137631		Soloway	6/16/1964	
	A 3	3594476		Merrill	7/20/1971	
	A 4	3715432		Merrill	2/6/1973	
	A 5	3755557		Jacobs	8/28/1973	
	A 6	3937668		Zolle	2/10/1976	
	A 7	3960757		Morishita et al.	6/1/1976	
	A 8	4053585		Allison et al.	10/11/1977	
	A 9	4056635		Glen et al.	11/1/1977	
	A 10	4073943		Wretlind et al.	2/14/1978	
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	A 13	4102806		Kondo et al.	7/25/1978	
	A 14	4107288		Oppenheim et al.	8/15/1978	
	A 15	4133874		Miller et al.	1/9/1979	
	A 16	4145410		Sears	3/20/1979	
	A 17	4147767		Yapel, Jr.	4/3/1979	
	A 18	4168308		Wretlind et al.	9/18/1979	
	A 19	4219548		Reller	8/26/1980	
	A 20	4235871		Papahadjopoulos et al.	11/25/1980	
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	A 22	4271196		Schmidt	6/2/1981	
	A 23	4298594		Sears et al.	11/3/1981	
	A 24	4302459		Steck et al.	11/24/1981	
	A 25	4308166		Marchetti et al.	12/29/1981	
	A 26	4309421		Ghyczy et al.	1/5/1982	
	A 27	4316884		Alam et al.	2/23/1982	
	A 28	4320121		Sears	3/16/1982	
	A 29	4328222		Schmidt	5/4/1982	
	A 30	4329332		Couvreur et al.	5/11/1982	
	A 31	4331654		Morris	5/25/1982	
	A 32	4332795		Ghyczy et al.	6/1/1982	
	A 33	4332796		Los	6/1/1982	
	A 34	4340594		Mizushima et al.	7/20/1982	
	A 35	4345588		Widder et al.	8/24/1982	
	A 36	4351831		Growdon et al.	9/28/1982	
	A 37	4356167		Kelly	10/26/1982	

Examiner Signature

Date Considered

\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 of 13

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
A 3 8	4369182			Ghyczy et al.	1/18/1983	
A 3 9	4371516			Gregory et al.	2/1/1983	
A 4 0	4378354			Ghyczy et al.	3/29/1983	
A 4 1	4394372			Taylor	7/19/1983	
A 4 2	4397846			Weiner et al.	8/9/1983	
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A 4 8	4448765			Ash et al.	5/15/1984	
A 4 9	4452817			Imperial Chemical Industrial	6/5/1984	
A 5 0	4483847			Augart	11/20/1984	
A 5 1	4485054			Mezei et al.	11/27/1984	
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A 5 3	4515736			Deamer	5/7/1985	
A 5 4	4522803			Lenk et al.	6/11/1985	
A 5 5	4610868			Fountain et al.	9/9/1986	
A 5 6	4613505			Mizushima et al.	9/23/1986	
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A 5 8	4629626			Miyata et al.	12/16/1986	
A 5 9	4675236			Ohkawara et al.	6/23/1987	
A 6 0	4687762			Fukushima et al.	8/18/1987	
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A 6 3	4725422			Miyabayashi et al.	2/16/1988	
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A 6 7	4766046			Abra et al.	8/23/1988	
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A 7 0	4798860			Parr	1/17/1989	
A 7 1	4800079			Boyer	1/24/1989	

Examiner Signature		Date Considered	
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Application Number 09/281,430

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First Named Inventor INDU PARIKH

Group Art Unit 1615

Examiner Name Todd Ware

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A 72	4801455		List et al.	1/31/1989	
	A 73	4803070		Cantrell et al.	2/7/1989	
	A 74	4806350		Gerber	2/21/1989	
	A 75	4806352		Cantrell	2/21/1989	
	A 76	4826687		Nerome et al.	5/2/1989	
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	A 89	5128147		Leveen et al.	7/7/1992	
	A 90	5145684		Liversidge et al.	9/8/1992	
	A 91	5152923		Weder et al.	10/6/1992	
	A 92	5164380		Carli et al.	11/17/1992	
	A 93	5167950		Lins	12/1/1992	
	A 94	5169847		Nagy nee Kriesfalussy et al.	12/8/1992	
	A 95	5178878		Wehling et al.	1/12/1992	
	A 96	5179079		Hansen et al.	1/12/1993	
	A 97	5217707		Szabo et al.	6/8/1993	
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	A 99	5256422		Micro Vesicular Sys., Inc.	10/26/1993	
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	A 101	5272137		Blasé et al.	12/21/1993	
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	A 103	5302401		Liversidge et al.	4/12/1994	
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	A 105	5314915		Rencher	5/24/1994	
	A 106	5326552		Na et al.	7/5/1994	
	A 107	5336507		Na et al.	8/9/1994	
	A 108	5338761		Nakajima et al.	8/16/1994	
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First Named Inventor INDU PARIKH

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Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
A 11 1	5352459			Hollister et al.	10/4/1994	
A 11 2	5360593			Bapatia	11/1/1994	
A 11 3	5364633			Hill et al.	11/15/1994	
A 11 4	5389377			Chagnon et al.	2/14/1995	
A 11 5	5399363			Liversidge et al.	3/21/1995	
A 11 6	5407683			Shively	4/18/1995	
A 11 7	5439055			Card et al.	8/8/1995	
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A 12 0	5478860			Wheeler et al.	12/26/1995	
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A 12 3	5498421			Grinstaff et al.	3/12/1996	
A 12 4	5510118			Bosch et al.	4/23/1996	
A 12 5	5518730			Fuisz	5/21/1996	
A 12 6	5527537			Dietl	6/18/1996	
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A 12 8	5536413			Bormann et al.	7/16/1996	
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A 13 2	5569448			Wong et al.	10/29/1996	
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A 13 5	5576016			Amselem et al.	11/19/1996	
A 13 6	5578325			Domb et al.	11/26/1996	
A 13 7	5589455			Woo	12/31/1996	
A 13 8	5589508			Schlotzer et al.	12/31/1996	

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First Named Inventor	INDU PARIKH
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Examiner Name	Todd Ware

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A 13 9	5603951		Woo	2/18/1997	
	A 14 0	5607694		Marx	3/4/1997	
	A 14 1	5618522		Kaleta et al.	4/8/1997	
	A 14 2	5631019		Marx	5/20/1997	
	A 14 3	5631023		Kearney et al.	5/20/1997	
	A 14 4	5637625		Haynes	6/10/1997	
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	A 14 6	5648375		Abraham	7/15/1997	
	A 14 7	5651982		Marx	7/29/1997	
	A 14 8	5651991		Sugiyama et al.	7/29/1997	
	A 14 9	5656286		Miranda et al.	8/12/1997	
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	A 15 1	5660837		Lundquist	8/26/1997	
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	A 15 9	5686102		Gross et al.	11/11/1997	
	A 16 0	5688528		Carlsson et al.	11/18/1997	
	A 16 1	5693337		Suzuki et al.	12/2/1997	
	A 16 2	5714520		Jones et al.	2/3/1998	
	A 16 3	5719197		Kanios et al.	2/17/1998	
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	A 16 5	5731356		Jones et al.	3/24/1998	
	A 16 6	5733572		Unger et al.	3/31/1998	

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Sheet

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Complet if Known

Application Number	09/281,430
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First Named Inventor	INDU PARIKH
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Examiner Name	Todd Ware

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	A167	5750142		Friedman et al.	5/12/1998	
	A168	5770222		Unger et al.	6/23/1998	
	A169	5773026		Schlipalius	6/30/1998	
	A170	5776491		Allen, Jr. et al.	7/7/1998	
	A171	5776495		Duclos et al.	7/7/1998	
	A172	5827520		Jones et al.	2/3/1998	
	A173	5827536		Laruelle	10/7/1998	
	A174	5827822		Floc'h et al.	10/27/1998	
	A175	5834025		de Garavilla et al.	11/10/1998	
	A176	5843465		Lundquist	12/1/1998	
	A177	5851275		Amidon et al.	12/22/1998	
	A178	5853755		Foldvari	12/29/1998	
	A179	5858398		Cho	1/12/1999	
	A180	5858410		Muller et al.	1/12/1999	
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	A182	5885597		Botknecht et al.	3/23/1999	
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	A184	5912007		Pan et al.	6/15/1999	
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet

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09/281,430

March 30, 1999

INDU PARIKH

1615

Todd Ware

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Attorney Docket Number 402076 SKYEPHARMA

### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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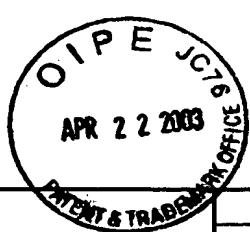
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 8 of 13 Attorney Docket Number 402076 SKYEPHARMA

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Application Number 09/281,430  
Filing Date March 30, 1999  
First Named Inventor INDU PARIKH  
Group Art Unit 1615  
Examiner Name Todd Ware

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### U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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### FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No <sup>++</sup>
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	A262		DE 2 938 807		Green Cross Corp.	11/13/1980		X <sup>+</sup>
	A263		DE 3 421 468		Dr. Rentschler Arzne. (see reference 4,880,634)	12/19/1985		X <sup>+</sup>
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	A267		EP 0 153 926		Duncan H. Haynes	6/14/1984		
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	A275		EP 0 499 299		Sterling Winthrop Inc.	8/19/1992		
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	A277		EP 0 580 690		Sandoz Ltd.	2/2/1994		
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Attorney Docket Number	402076 SKYEPHARMA

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### FOREIGN PATENT DOCUMENTS

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		Office	Application or Patent Number	Kind Code			Yes	No <sup>+</sup>
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A 286		GB	1 527 638		Laboratories Fournier	3/20/1996		
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Application Number	09/281,430
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Group Art Unit	1615
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Attorney Docket Number	402076 SKYEPHARMA

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### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes      No <sup>++</sup>
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09/281,430

March 30, 1999

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Todd Ware

Attorney Docket Number

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### OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
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	A 35 7	MISHRA et al., "Scientifically Speaking: Novel Injectable Formulations of Water-Insoluble Drugs", <i>Controlled Release Newsletter</i> , Vol. 17, Issue 2, (June 2000), pp. 21-30	
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	A 36 7	Website <a href="http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm">http://userpage.fu-berlin.de/~kayser/nanosuspensionen.htm</a>	
	A 36 8	WU et al., "Pharmacokinetics of Methoxyflurane After Its Intra-Dermal Injection as Lecithin-Coated Microdroplets", <i>Journal of Controlled Release</i> , (1989), Vol. 9, pp. 1-12	
	A 36 9	ZUIDAM et al."Sterilization of Liposomes by Heat Treatment", <i>Pharmaceutical Research</i> , Vol. 10, No. 11, 1993 pg 1591-1596	

Examiner Signature		Date Considered
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\* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).

+ An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3)